BIOTECHNOLOGY:

a Development Plan for Canada

Report of the Task Force on Biotechnology to the Minister of State for Science and Technology

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Ottawa, February 18, 1981

The Honourable John Roberts
Minister of State for
Science and Technology
Ottawa, Ontario

Sir:
I have the honour to present to you herewith the report of the Task Force that was established, in June 1980, to investigate the opportunities offered to Canada by biotechnology.

Sincerely yours,

Maurice Brossard

Maurice Brossard
Chairman of the Task Force

FOREWORD

On June 10, 1980 the Minister of State for Science and Technology, the Honourable John Roberts, announced the establishment of a Task Force on Biotechnology. In so doing the Minister stated that "biotechnology held an enormous development potential and that it was essential that Canada take full advantage of the opportunities presented."

The terms of reference of the Task Force were:

i) to advise the Minister on the possibility and suitability of instituting specific policies and programmes designed to allow Canada to take advantage of the opportunities offered by biotechnology; and more particularly

ii) to identify those areas of research and development of biotechnology in which Canada might most appropriately specialize, given its economic and social structure;

iii) to review possible ways of encouraging and promoting the required research and development and assuring that the results of this research and development will be used to meet economic and social development needs;

iv) to consult as required with industry, universities and government; and

v) to submit recommendations to the Minister, including a plan of action to ensure that Canada can take full advantage of the advances in biotechnology, keeping in mind the respective but mutually supportive roles of government, industry and universities.

The members of the Task Force were:

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Throughout its deliberations the Task Force was well aware of the advantages of a "market-pull" rather than a "technology-push" approach to industrial development. However, the almost total absence of biotechnology industrial activity in Canada necessitated recommendations supporting a technology orientation, at least in the short term, for this country's development of biotechnology.

Although biotechnology is only one of several high technology areas (microelectronics, robotics, etc.) currently receiving attention throughout the industrialized world, the Task Force did not feel that it was within its mandate to comment upon the order of priority of biotechnology in relation to these other technologies.

The Task Force was greatly aided in its deliberations by the contributions of many individuals, groups, societies, and institutions. The occurrence of many conferences, workshops, and seminars throughout the lifetime of the Task Force afforded the opportunity of close interaction with national and international participants in the field of biotechnology.

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EXECUTIVE SUMMARY AND RECOMMENDATIONS

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The prospects for future industrial growth in Canada will depend primarily upon the pathways chosen for expanded economic development. One such pathway which should be pursued on a national basis is that which relates to the growth and development of high technology industries. High technology industries have high rates of growth, productivity and employment and offer the most reasonable chance to create new markets or redefine existing ones, all on a world scale. One new area of high technology which offers significant opportunities for Canada is biotechnology.

Biotechnology is an area of high technology which is based upon the unique characteristics of biological materials such as microbial, plant or animal cells and enzymes. It offers the opportunity to develop new industries as well as to revitalize established ones by the use of processes which, in the production of new or existing products, require significantly less energy than existing ones. These processes may primarily depend upon renewable rather than non-renewable resources for starting material and can be significantly less harmful to the environment. The opportunities offered by biotechnology are presently being pursued in numerous areas of research and industry throughout the world.

Biotechnology and its accompanying techniques represent a spectacular advance in the growth of modern fermentation and major developments will continue to unfold from advances in interdisciplinary approaches to scientific research. A strong interdisciplinary science base is crucial to the continuing development of biotechnology, in particular the ability to adapt biological processes to specific needs. The erosion of science in Canadian universities and government research establishments over the past decade has weakened Canada's current ability to respond to the challenges of biotechnology. The strengthening of this science base is therefore a critical priority for the future development of biotechnology in Canada.

There are five major techniques which have greatly expanded the scope of fermentation technology and which are the basis of what is currently considered to be biotechnology. These are: (1) genetic engineering; (2) enzymes and enzyme systems; (3) fused-cell techniques; (4) plant-cell culture; and (5) process and systems engineering. These five techniques will have major impacts on food and agriculture, forestry and forest products, energy, waste treatment and pollution control, health care products, chemicals and mining. Canada, whose economy is so heavily dependent upon its resource sectors, must begin immediately to explore the various opportunities offered by

biotechnology. If Canada's resource industries fail to innovate through biotechnology, their competitiveness in world markets will be jeopardized.

For Canada, the application of biotechnology to nitrogen fixation, novel aspects of cellulose utilization, the development of plant strains, the treatment and utilization of wastes and mineral leaching are major priorities for industrial development. Moreover, the development of needed health care products is necessary for the country's social as well as economic development. Unless the natural resource-related activities are pursued vigorously, it is unlikely that international developments in these areas will be adaptable to the Canadian milieu. Apathy towards biotechnology would result in the loss of an important opportunity to successfully manage Canada's resource advantages, and at the same time develop a strong network of high technology industries.

Canada's current biotechnological efforts are characterized by a wide scattering of research activitiy in university and government (federal and provincial) laboratories and the absence of any major industrial activity. Therefore, a major effort is required to stimulate the growth of an industrial sector based upon biotechnology, and at the same time to promote a focussing of the country's research efforts in this area.

In order to start building an appropriate biotechnological industry and the necessary supporting scientific and technical infrastructure, a long-term National Biotechnology Development Plan for Canada is proposed. This plan has eight elements which are the basis for the following recommendations:

1. Commitment

A long-term commitment by all sectors is mandatory to the successful realization of the potentials of biotechnology. It is recommended that the federal government establish a ten-year National Biotechnology Development Plan. For the first year of the Plan a federal allocation of $33 million is recommended, rising to an average annual expenditure of $50 million over the lifetime of the Plan. This expenditure is intended as a catalyst to encourage industry and provincial governments to make substantial investments in biotechnology.

2. Industrial Stimulation

To create the appropriate climate for industrial growth in biotechnology, it is recommended that the present 100 percent write-off for research and development (R and D) expenditures, as well as the 50 percent deduction for incremental R and D expenditures and other tax credits, all be replaced by a 150

percent write-off of all biotechnology industrial R and D expenditures incurred. It is further recommended that investors in biotechnological industries be permitted a 100 percent write-off of investment expenses against income from any source, as well as a 66 2/3 percent incremental investment write-off similar to that formerly allowed for frontier oil and gas exploration investments.

Government procurement programs can be an effective means of promoting industrial growth. It is therefore recommended that a Biotechnology R and D Panel (see Organization p. 7) play an advisory role for governments in commenting upon procurement action for Canadian biotechnological industrial development.

To encourage small-and medium-size biotechnological industries, direct government assistance is recommended in the form of an additional $6 million in 1981-82 to the Enterprise Development Program of Industry, Trade and Commerce.

To promote effective transfer of biotechnological advances from government laboratories to the private sector, it is recommended that $5 million be added to the recently consolidated Program for Industry/Laboratory Projects (PILP) — Cooperative Projects with Industry (COPI) program for 1981-82. To promote technology transfer from universities to industry it is also recommended that $0.7 million be added to the Project Research Applicable to Industry (PRAI) program of the Natural Sciences and Engineering Research Council (NSERC) for 1981-82.

Technology transfer also requires effective communication amongst all sectors. It is recommended that $0.3 million be added to the conference budgets of the NSERC, the Medical Research Council (MRC) and the National Research Council (NRC) respectively, to facilitate these types of technological interaction in the field of biotechnology.

Finally, to provide salary support for research personnel in biotechnological industries or to people working on projects relevant to a particular biotechnological industry, it is recommended that for 1981-82 the total budget for the Industrial Research Assistance Program (IRAP) of the NRC be increased by $3 million.

3. Interdisciplinary Science Base

To provide the science base appropriate to the successful development of biotechnology, it is recommended that the 1981-82 operating budgets of the NSERC and the MRC be increased by $4.7 million and $2 million respectively and that these funds be used to encourage interdisciplinary efforts focussed on the needs for industrial biotechnology.

Both the Division of Biological Sciences and the Prairie Regional Laboratory of the NRC are sources of interdisciplinary science strength related to biotechnology. It is recommended that eight person-years and $2.5 million be added to the budget of the Division of Biological Sciences and six person-years and $0.8 million to the budget of the Prairie Regional Laboratory for 1981-82 to pursue this development.

4. Manpower

Unless properly trained manpower is available to meet the demands by all sectors, the development of biotechnology in Canada will be severely impeded. For the purpose of providing interdisciplinary training support for biotechnological manpower, it is recommended that the graduate and post-graduate training programs of the NSERC and the MRC be increased by $3 million and $1.4 million respectively for 1981-82. In addition to these traditional programs, these Councils should consider support for graduate training in government and industry research establishments associated with a Canadian university graduate school, as well as industrial postdoctoral support tenable outside Canada. It is further recommended that immigration priorities actively address the immediate shortage of biotechnological skills which are in high demand world-wide. Finally, universities, technical colleges and their respective provincial governments should be encouraged to collaborate immediately on the development of new curricula which more adequately reflect the interdisciplinary, multi-faceted, and industrial nature of biotechnology.

5. Directions

Several areas of application of biotechnology are seen as crucial to Canada's future economic and social performance. It is recommended that the current nitrogen fixation programs of the Prairie Regional Laboratory of the NRC and Agriculture Canada be combined, located in two centres, namely Saskatoon and Ottawa, and that five person-years and $1 million be added to each of these establishments for 1981-82. Forest-related nitrogen fixation research requires rapid development and it is recommended that a plan to concentrate resources be developed by the Canadian Forestry Service of Environment Canada and submitted to the Biotechnology R and D Panel (See Organization p.7).

For novel aspects of cellulose utilization and waste treatment, it is recommended that Environment Canada and the NRC jointly undertake studies of how the activities of each department might be combined and strengthened in order to maximize support for industrial development in these two distinct areas. Industrial involvement in the preparation of the studies will be essential. In

addition, it is recommended that Environment Canada examine ways to strengthen the Forest Pest Management Institute at Sault Ste. Marie, as one means of addressing some of the problems of preserving the cellulosic base.

For plant strain development, it is recommended that ten person-years and $1 million be added in 1981-82 to permit Agriculture Canada to augment its existing R and D activities in this area, through the exploitation of biotechnology.

For mineral leaching, it is recommended that an additional $1 million be made available to Energy, Mines and Resources Canada in 1981-82 to promote the further development of Canadian expertise in this area.

6. Regulation

Section 41 of the Canadian Patent Act has had a negative effect upon the growth of the health care product industry in Canada. It is recommended that this section be abolished and also that a general review of the Patent Act be undertaken to ensure that the Act is not leaving Canada at a disadvantage relative to other nations with respect to industrial R and D investment.

Bill C-32, Plant Breeders Rights, could be an important stimulus to the expansion of the Canadian plant breeding industry. Since the development of new plant strains will be heavily affected by biotechnology and since it is an important area to be pursued by Canada, this bill should be given careful consideration. The compulsory licensing provision of the Bill should be given special attention to ensure that it does not defeat the intent of the legislation.

Finally, it is recommended that the MRC continue to administer the guidelines for the handling of recombinant DNA molecules, animal viruses and cells, and at the same time continue its practice of ongoing modification of the guidelines as new knowledge becomes available. It is also recommended that Health and Welfare Canada (HWC) establish a system of voluntary compliance for industry with respect to the guidelines.

7. International Collaboration

To ensure that Canadian scientists can contribute to and benefit from international efforts in biotechnology, it is recommended that the NSERC, the NRC and the MRC use existing program instruments to promote this activity. Government scientists are also encouraged to pursue these collaborations.

8. Organization

The National Biotechnology Development Plan will require a management group to guide and evaluate the Plan as it matures. The Task Force therefore recommends that a Biotechnology Research and Development Panel be established to oversee the resource allocations of the Plan, to keep abreast of a rapidly evolving field and to provide advice on biotechnology to all sectors. Industrial representation should be a major element in the Panel's composition and the provinces should be encouraged to participate collectively in the deliberations and activities of the Panel.

1. INTRODUCTION

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The prosperity and growth of several industrialized countries, including Canada, in the 1960's was less a result of innovation, new technology, export initiative and general entrepreneurship, than a function of a rapidly expanding labour force and what was then viewed as an inexhaustible supply of natural resources. At the same time other countries made a conscious effort to expand their innovative capacity. As a result Canada, among others, is now faced with a serious decline in its industrial technological capability relative to its international competitors.

For Canada, its share of world exports has fallen from 5.4 percent in 1970 to less than 3.0 percent in 1978. During the same period imports have increased from approximately 26 percent to 38 percent of the domestic market. In eighteen of nineteen high-technology groups of industries monitored by the Trade Analysis Branch of Statistics Canada, there have been growing deficits since 1970.(1)

There is considerable evidence to show that the prospects for continued growth in an increasingly industrial economy will depend on a country's capacity for the development of high technology.(2) Industries based upon high technology have higher R and D intensities, triple the growth rate, twice the productivity, significantly greater rates of employment and less inflation in their prices, than industries not based upon high technology.(3)

In a world beset by shrinking energy resources, escalating health care costs, petroleum dependence, imbalances in food supply, and environmental pollution, an area of high technology has emerged which offers substantial promise towards the alleviation of some of these ills. This area of high technology is known as biotechnology.

Biotechnology is defined as the utilization of a biological process, be it via microbial, plant or animal cells, or their constituents, to provide goods and services.

For centuries mankind has exploited biological processes through the techniques of fermentation to produce alcoholic beverages, develop new foods and to detoxify human and animal

(1) *Uncertain Prospects. Canadian Manufacturing Industry 1971-77.* Science Council of Canada, October 1977.

(2) For the purpose of this report high-technology industries are defined as those industries which depend upon their innovative capacity to advance their product or process and thereby maintain their competitive edge. A significant commitment to research and development is an important factor in ensuring the development of this innovative capacity.

(3) *Performance of Canadian Manufacturing Industries by Levels of Research Intensity* MOSST Background Paper Number 4, July 1978.

wastes. In the first part of the twentieth century advances in fermentation technology gave rise to useful vaccines and several industrial processes for the production of organic acids and solvents. There followed a period of rapid development in microbiology, culminating in the production of a variety of products, including antibiotics, amino acids, vitamins, gums and steroids, all via the process of fermentation.

In recent years, however, spectacular advances in cellular and molecular biology, biochemistry, microbial genetics and biochemical engineering have greatly magnified the range of applications to which biological processes can be directed, thus extending the range of fermentation processes. It is this broadened range of fermentation which is now known as biotechnology.

Although Canadian scientists have contributed and are continuing to contribute to advances in the basic understanding of fermentation processes, there has as yet been little Canadian industrial interest in pursuing the commercial opportunities offered by biotechnology.

Throughout the world production of fuels from renewable resources, recovery of raw materials, novel methods of crop fertilization and plant breeding, waste treatment and pollution control, the development of health-care products, new feedstuffs, new sources of petrochemicals, and highly selective methods of pest control are being pursued through the development and application of biotechnology.

Of particular interest is biotechnology's potential economic impact. By offering processes requiring significantly lower inputs of energy than conventional ones, biotechnology may offer alternate approaches for existing industries whose energy costs have become major concerns. In addition to new product development, several of the biotechnological processes offer new pathways to existing products normally derived from non-renewable resources. Through exploitation of renewable resources, these new biotechnological processes could substantially reduce the pressures of inflation which plague commodities presently based on non-renewable resources.

Another attractive feature of biotechnology is that the resulting processes are generally less polluting than the processes they replace. In addition, the application of biotechnology to the treatment of wastes can result in, not only a net benefit to the environment, but also, the concomitant production of alternate feedstuffs and environmentally acceptable fertilizers.

Many countries throughout the world have recognized the importance of biotechnology to their respective industrial futures and have initiated long-range strategies to capitalize upon its future potential. For example, West Germany has targeted $28

million for biotechnological R and D in 1980 as the first year in a five-year investment plan. This comes after an investment in biotechnology of $100 million since 1972. In France, a $28 billion joint government-industry technological development plan for five years has specified biotechnology as one of five key areas[4] to be promoted. In the United Kingdom, government support of biotechnology R and D is projected at $35 million per year through 1985, in addition to an investment of $6 million per year in a jointly sponsored commercial venture between government and industry. Japan, whose existing biotechnological industry accounts for nearly 5 per cent of that country's GNP, will allocate $23 million in 1980 for biotechnology R and D through government sources.

These investments in biotechnology by industries and governments are evidence of the universal recognition that this area of high technology will begin to create major industrial changes within the next decade. If Canada expects to participate in these changes, then businesses, governments and educational institutions will need to take strong, positive action immediately.

Biotechnology offers a wide range of industrial opportunities for both new and existing industries. Canada, whose economy is so heavily dependent upon its resource sectors, namely energy, mining, food, agriculture and forestry, could benefit substantially from the appropriate applications of biotechnology. If for no other reason than the necessity of maintaining a competitive marketing position with respect to other countries, Canada's resource-based industries in particular must now accelerate their exploration of the exciting possibilities offered by biotechnology.

(4) France's five-year plan identifies biotechnology, electronics, ocean mineral exploration, aerospace and mechanical design as the technologies to be promoted.

2. BIOTECHNOLOGY IN CANADA: AN OVERVIEW

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A practically non-existent biotechnological industrial base, a rapidly shrinking federal government research capability and a highly fragmented and unfocussed university effort are the major features of Canada's current biotechnological activities. Although the MOSST Background Paper No. 11 *Biotechnology in Canada* (June 1980) identifies numerous individuals and companies involved in biotechnology, the overall level of that activity, given the enormous breadth and R and D requirements of the field, is extremely low.

It is the lack of major industrial presence and the unfocussed nature of Canada's research efforts in biotechnology which formed the backdrop against which the various biotechnological opportunities were examined by the Task Force and the directions for Canada elucidated.

3. THE OPPORTUNITIES AND PRIORITIES

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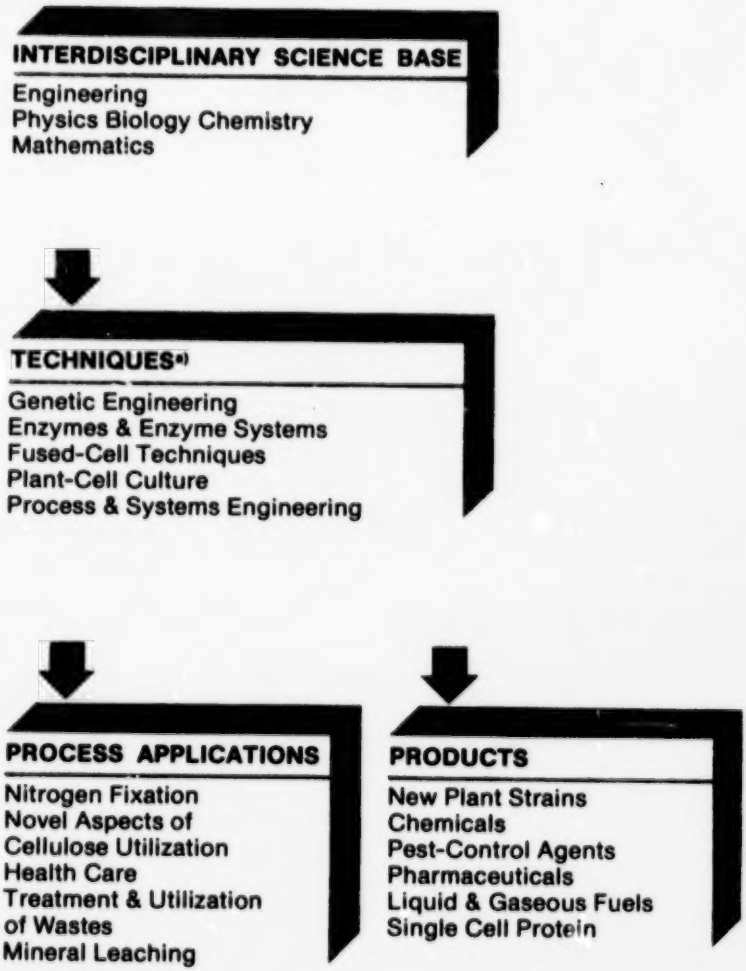
Biotechnology is now emerging as a vehicle for the production of goods and services because of interdisciplinary advances in the sciences of biology, chemistry, physics, mathematics and engineering. This interdisciplinary science base provides the sources from which the requisite techniques have flowed and will continue to flow, leading to the various applications and products which represent the range of industrial opportunities of potential interest to Canada. It is therefore imperative that the interdisciplinary science base and its technological offspring be strong and well developed in order to provide a solid nucleus for industrial growth and continued profitable activity. This flow of biotechnological development, from interdisciplinary science base to process applications and products, is outlined in Figure 1.

A. INTERDISCIPLINARY SCIENCE BASE

Interdisciplinary approaches to scientific development are the keys to the very large potential offered by biotechnology. Chemical and biochemical engineering, microbiology, applied genetics, molecular biology, biochemistry, toxicology, biostatistics, forest and foods chemistry, physiology and parasitology are some of the disciplines, sub-disciplines and areas of specialization which must be fostered and inter-related if these potentials are to be realized. If the interdisciplinary science base remains weak and unfocussed, not only will the indigenous development of biotechnology in Canada be diminished, but the ability to acquire and adapt techniques from other countries will be severely impaired.

In Canada the poor economic climate for industrial research, the erosion of support for research in universities and government laboratories, and the broad distribution of the limited resources available over the past decade have resulted in a scientific community which is poorly situated in an interdisciplinary as well as an industrially oriented sense, to rise to the challenges of the biotechnological age. A further ramification of this situation has been the production of research personnel without the appropriate skills needed for biotechnology. The building and strengthening of Canada's interdisciplinary science base is therefore a major priority for the development of biotechnology in Canada.

FIGURE 1
Pathway of Biotechnological Development



a) It should be noted that each of the techniques listed will have a major impact upon future developments in the overall field of fermentation, and that it will be through fermentation that many of the products and process applications will be realized.

B. THE TECHNIQUES

Out of the interdisciplinary science base and the advancement of knowledge have come the techniques which are the foundation of modern fermentation, and the infrastructure for the future industrial exploitation of biological processes. The five major techniques are: (i) genetic engineering; (ii) enzymes and enzyme systems; (iii) fused-cell techniques; (iv) plant-cell culture; and (v) process and systems engineering.

Genetic Engineering[5]

Genetic engineering or recombinant DNA techniques are the terms which identify a recent development in molecular biology, namely the ability to take selected fragments of DNA from the cells of a plant or animal, from microorganisms, or as products of chemical synthesis, join these fragments to another piece of DNA and then transfer the reconstructed DNA to a microorganism. Through the exploitation of this technique, a microorganism can thereby acquire novel genetic properties and the resultant ability to create a new product, or to use and/or transform a particular substrate. The areas of application for this technique are enormous, ranging from the production of health care products such as insulin, interferon, human growth hormone etc., to the greater flexibility of yeasts in the manufacture of alcohols, to the direct conversion of cellulose and starch into fermentable carbohydrate and other chemical intermediates, to a broadening of understanding of cellular regulation and the adaptability of microorganisms. Genetic engineering is therefore viewed as having a high priority for the development of biotechnology.

In Canada, present emphasis on genetic engineering resides almost exclusively in universities and the National Research Council. While there are excellent individuals pursuing this area of research in several universities, the work is badly fragmented with the result that there is no unifying theme or focus. At the National Research Council, considerable expertise has developed in genetic engineering, but the effort in no way approaches the necessary "critical mass" upon which a relatively large industrial interest could draw.

Enzymes and Enzyme Systems

The use of enzymes in industry, health care and research has steadily increased over the last two decades. Traditionally, enzymes from natural sources have found considerable utility in

(5) Although genetic engineering is considered, in this report, as primarily a technique applicable to microorganisms, it should be noted that future applications of this technique to higher organisms, namely plants and animals, could conceivably result in greater control over genetic expression and regulation in these life forms. Examples of possible future developments in this area are disease treatment through gene therapy and inter-species transfer of desirable characteristics.

the food industry and as a result several established firms in Japan, the United States, Denmark and Germany expanded their activities to include the supply of these enzymes from a variety of sources. The lack of a comparable enzyme industry in Canada militates against any recommendation that a similar industry based upon conventional production techniques be promoted.

However, the recent identification of particular microorganisms as sources for the supply of both current and new enzymes has created a new dimension to enzyme supply. Genetic engineering could also markedly enhance the capacity of microorganisms to produce enzymes and could conceivably result in the production of enzymes whose characteristics have been "tailor-made" for particular requirements.

In terms of utilization, the ability to immobilize enzymes holds great promise for future industrial processes. Currently limited in part by enzyme supply, this adaptation of enzyme technology permits the development of new flow processes which are characterized by increased enzyme stability and greater control over enzymatic efficiencies. Moreover, the use of bacteria, yeasts, fungi, plant and animal cells as immobilized multi-enzyme systems offers the additional advantage of accomplishing complex transformations which, when addressed by conventional chemical processes, are extremely costly, time consuming and inefficient.

Thus both new and existing products can be produced by the application of enzyme techniques. The major opportunity for the use of enzymes may derive from the growth of biotechnology itself, since the processing of renewable resources for fermentation will require new applications of enzyme technology. Therefore, enzymes and enzyme systems, in a novel as opposed to a conventional sense, represent another high priority technique for Canada's industrial future in biotechnology.

In addition to the lack of a Canadian enzyme industry, the Canadian expertise in enzymology centres around the academic aspects of the subject. As a result, there has been little effort to translate the basic knowledge of enzymes into industrial processes. In the few cases where an industrial orientation to enzyme research has emerged, there has not been a synchronous development of research on the related fundamental aspects of enzymes. It is essential, for the effective development of a Canadian industrial capability in enzyme techniques, that both the applied and fundamental research activities be developed in a coordinated fashion.

Fused-Cell Techniques

In principle, the ability to fuse any two cells to produce a hybrid entity opens up a myriad of opportunities in the fields of agriculture and forestry as well as in the production of new health care products. In the agricultural and forestry areas, recent

developments have shown that plant cells can be fused to result in hybrid plants. This technique might ultimately lead to plants which exhibit faster growth, atmospheric nitrogen fixing capabilities, greater disease and climatic resistance and overall, more advantageous characteristics. The whole nature of plant strain development, a current feature of long-term agricultural and forestry research, could therefore be revolutionized with the large-scale application of these techniques.

Another aspect of fused-cell techniques has been the development of the ability to fuse a neoplastic cell with any cell which is capable of making a useful biological entity, thereby rendering the resulting hybrid capable of unrestricted growth. This application of fused cells, sometimes referred to as hybridomas, will create a new dimension to the production of diagnostic and therapeutic agents. To date, hybridomas are being exploited commercially in other countries for the production of monoclonal antibodies. These antibodies could soon be the source of pure vaccines and highly specific diagnostic reagents, as well as agents for the effective purification of a great range of desired products.

A considerable number of Canadian investigators have begun to investigate fused-cell techniques, with both monoclonal antibodies and plant strain development receiving attention. There has been, however, little effort to coordinate these activities and few attempts to develop the commercial possibilities.

Canada's economic dependence upon its agricultural and forestry base, as well as its need for a broadening of its health care products industry, exemplify the need for continued inventiveness in these areas in order to remain competitive. Applications of fused-cell techniques are seen as one means of addressing these issues and therefore this area has a high priority for Canada's biotechnological development.

Plant-Cell Culture

For centuries plants have been a rich source of medicinal agents, but climatic variations, difficulties of supply and vanishing species have spurred the search for alternative means of obtaining these agents. As a technique, the culturing of plant cells *in vitro* is considered a viable means of providing required substances, thereby avoiding the necessity of whole plant cultivation. In addition, plant cells are now being examined as vehicles of biotransformation, in much the same manner that microbial cells and enzyme systems are being examined.

Canada possesses world class expertise in plant-cell culture technology at the Prairie Regional Laboratory of the National Research Council. However, unless efforts are made to strengthen this base, its current lead will soon evaporate as other countries build their own capabilities in this technological area.

The difficulties of conducting remunerative pharmaceutical R and D in Canada (see Pharmaceuticals p. 26) and the current application of plant cell techniques to the production of medicinals raise many questions as to the Canadian future for this particular aspect of biotechnology.

Process and Systems Engineering

The very nature of biological or microbial operations, products and techniques requires special processing procedures and precautions, handling and control. This, in turn, imposes very special requirements on engineers and designers of the process and systems equipment and accessories. Process and systems engineering therefore play a central role in the initiation, application and commercialization of biotechnology. For this reason, process and systems engineering are considered high-priority elements in the development of Canada's industrial biotechnological effort.

Future developments in process and systems engineering will undoubtedly focus on process kinetics, fermentation reactor design, the creation of new biological and physical sensor equipment, computer applications as well as the design of specialized instruments and apparatus. It is therefore evident that as a Canadian biotechnology industry develops, opportunities will also arise in the industries which serve it.

The current lack of large-scale exploitation of biotechnology in Canada is reflected in the lack of coherent specialized process and systems engineering expertise. Unless major efforts are made to begin building the appropriate engineering skills, the long-term initiatives in other facets of biotechnology will, sooner or later, come up against a significant hurdle in the translation of research results to commercial processes.

C. PROCESS APPLICATIONS

The techniques of genetic engineering, enzymes and enzyme systems, fused cells, plant-cell culture and process and systems engineering will have a significant impact upon numerous present and future industrial processes. From a Canadian perspective there are five major process applications of biotechnology which, if vigorously pursued, could result in substantial economic benefit. These process applications are nitrogen fixation, novel aspects of cellulose utilization, health care, treatment and utilization of wastes, and mineral leaching.

Nitrogen Fixation

The importance of nitrogen as an integral element in agricultural and forest production, coupled with the escalating cost of nitrogen fertilizers from petrochemical feedstocks, make the conversion of atmospheric nitrogen into an acceptable plant fertilizer by biological processes a high priority issue for Canada.

It is well known that part of the responsibility for the uptake of nitrogen by legumes and alder species rests with microorganisms. Current research world-wide is now being directed along several lines as a means of capitalizing upon this biological phenomenon in application to non-nitrogen fixing crops. Crop breeding techniques, genetic engineering and genetic manipulation are some of the present avenues of investigation.

In Canada, both the Prairie Regional Laboratory of the National Research Council and Agriculture Canada have been involved in nitrogen fixation research related to agriculture. This effort, however, has been diminishing for want of personnel and resources, especially at the National Research Council. The Energy From the Forest (ENFOR) Program of Environment Canada has supported research on nitrogen fixation related to forestry over the past few years. If Canada is to benefit substantially from this process application of biotechnology, a much greater focus and strengthening of its overall effort must take place.

Although the returns from research and development efforts related to nitrogen fixation are not expected to be realized for perhaps a decade or more, the great reliance of Canada's economy on its agricultural and forestry sectors argues strongly for a major Canadian effort in this high priority area of application of biotechnology.

Novel Aspects of Cellulose Utilization

Canada's large agricultural and forestry resources represent an important opportunity for novel approaches to cellulose utilization. Cellulose is a renewable resource which could represent a major source of carbohydrate for Canada. Methods for the economical conversion of cellulosic residues and wastes into more readily fermentable carbohydrate will open up a range of potential product options including chemicals, solvents, foodstuffs and fuels.

As a means of broadening the forestry and agricultural management base, biotechnological applications to cellulose utilization may make a significant impact. Cellulose pretreatment processes, coupled with microbial or enzymatic hydrolytic procedures, are currently receiving a great deal of attention, as are various mechanical/chemical/thermal processes with which biotechnological approaches must compete. The forestry industry in particular, which made a net contribution of nearly $12 billion in 1979 to Canada's trade balance (more than the agriculture, food, beverage, fish, coal, petroleum, mining and chemical sectors combined), is in danger of losing its world competitive position because of its slow pace of innovation stemming from a comparatively low level of investment in research. One means of pursuing the more effective utilization of

the forest resource, and thereby expanding the versatility of the industry itself, will be the investigation of biotechnological methods for cellulose utilization and conversion.

The Pulp and Paper Research Institute of Canada, the National Research Council and several universities are actively exploring novel aspects of cellulose utilization. Because of the large economic impact it could have upon the agricultural and forestry sectors, the application of biotechnology to cellulose utilization is considered a high priority for Canada.

Health Care

Adequate health care is a crucial element in a nation's social and economic development. Biotechnology has had and will continue to have a major impact upon the quality of health care available, both from the viewpoint of developing new agents for disease control and from the viewpoint of introducing new strategies for disease prevention. It is important to note that it is in the health care area that some of the first products of recent biotechnological advances are coming to usable and marketable form, of which insulin for the treatment of diabetics is a cogent example.

Within the next several years, large quantities of human hormones, human interferon, human blood proteins, specific human antibodies and vaccines, and viral antigens (for use as vaccines) will become available as a result of the application of techniques such as genetic engineering and fused cells. As important as these products will be, they represent only the first generation of future influences of biotechnology upon the nature of health care. For example, with increasing knowledge of cellular and genetic regulation will come improved understandings of cancer and hereditary diseases and the subsequent development of specifically designed therapies.

In order for Canada to be able to continue to deliver high quality health care to its citizenry, it is therefore mandatory that we build and maintain the scientific and industrial capacity to keep abreast of and make contributions to advances in the health care applications of biotechnology.

Treatment and Utilization of Wastes

Biological processes offer significant advantages over other methods for detoxification of effluents and the transformation of waste into useful products.

Two of these advantages are (i) the adaptability of biological processes to the varying composition of waste and conditions of its degradation and (ii) the availability of a large spectrum of mixed-action cultures of microorganisms which can degrade a wide variety of substances. Biotechnology is already established as a means of treating waste streams from domestic sources and from industries which process large volumes of natural materials.

Current research is directed at improving the cost-effectiveness of treatment methods and improving the economics of converting forest and agricultural wastes and residues into useful by-products.

The increased pressure upon new and existing industries to invest more heavily in waste treatment and pollution control could spur more development in this application of biotechnology. However, the absence of coordination in Canada's current R and D effort in this area, together with a paucity of work on the degradation of recalcitrant toxic materials, will severely limit future progress.

Mineral Leaching

For centuries, man has been aware of the acid drainage originating from coal workings, copper mines and waste dumps. It has only recently been shown that the agent responsible for this phenomenon is a microorganism, *Thiobacillus ferrooxidans.* Numerous studies have subsequently revealed that *Thiobacillus ferrooxidans* can, under suitable conditions, attack mineral sulfides and convert these minerals into a solubilizable form. At present, this application of biotechnology is being exploited world-wide as a cost-effective method for the recovery of copper and uranium. Other metals such as nickel and zinc are also potentially amenable to extraction by this process.

Microbial leaching of minerals has found its greatest application thus far in dump leaching, particularly for low grade ores found in mine tailings. However, concentrate leaching is now being actively explored as an alternative to conventional mining processes.

Whereas conventional pyrometallurgy is greatly dependent upon energy sources, dump leaching via biotechnology is only slightly energy dependent. Moreover, the biotechnological approach does not require expensive pollution control equipment. As a result, many mining operations under development throughout the world are including a dump leach operation of low grade wastes as a significant economic factor in total mine development.

In Canada, the B.C. Research Council represents an internationally recognized authority on the scientific, technical and industrial exploitation of microbial leaching. While industrial concerns in other countries are rapidly adopting this new technology, very little interest is evident in Canada. Any attempt to strengthen Canada's scientific and technical base in this area should be focussed on the existing expertise with concomitant encouragement to industry to take advantage of this Canadian capability. The importance of Canada's mining industry to the country's overall economic performance, coupled with this strong base of expertise in mineral leaching, substantiates this as a high priority area for the application of biotechnology in Canada.

D. PRODUCTS

The possible production of an almost infinite range of products is being claimed world-wide through the application of the techniques which make up biotechnology. A few of these products are described below. In terms of priorities for product development, however, it is the Task Force's opinion that industry must decide, on the basis of market evaluation, when the time is ripe to develop specific products by application of biotechnology. There may be circumstances, however, particularly in product categories requiring long development times, in which government may be required to take the initial lead.

New Plant Strains

The application of genetic engineering and fused-cell techniques to plant strain development will have a major impact upon both the agricultural and forestry sectors in the decades ahead. The possibilities of developing plants which can fix atmospheric nitrogen, exhibit greater pest tolerance, frost resistance, early maturity, high nutritional value, and which can survive under arid and highly saline conditions, are now being pursued elsewhere.

The importance to Canada of new plant strain development using biotechnology must be recognized. The plant strains developed in other countries will not be readily transferred outside the milieu for which they were designed. Unless Canada develops the appropriate technological expertise, the development of new plant strains which are suitable to Canadian climates, soil conditions, and pest and weed conditions is unlikely.

Chemicals

Most of the chemical feedstocks required by industrialized countries (including those now derived from petroleum) could be supplied from biological sources and processes. Cellulosics, microbial polysaccharides, lignin derivatives, levulinic, lactic and other fatty acids, ethanol, acetone, butanol, vegetable oils for plasticizers, lubricants and rubbers are a few examples. Since the production of these chemicals is directly amenable to new and better processing and the development of new feedstocks, the applications of genetic engineering, enzyme techniques and process engineering could dramatically affect the supply of these commodities in the foreseeable future.

Speciality chemicals such as additives, coatings, fragrances, monomers for speciality plastics and biopolymer modifications may be much more accessible by biological or biologically derived processing methods than by traditional chemical approaches. Opportunities also exist in the development of plants and plant cells grown specially to produce single complex chemicals. In the speciality chemical field, therefore, the application of plant-cell culture techniques to the transformation or fermentation processing of biological feedstocks such as glucose presents numerous opportunities.

Major gaps exist in our current knowledge of the metabolic pathways, regulation and genetics of microorganisms and cells. Current Canadian efforts in this biotechnological area are small and fail to reflect an appreciation of the broader applications to which this research might relate.

Pest-Control Agents

In recent years there has been a strong trend away from chemical insect control strategies towards biological control strategies. The reasons for this movement include (i) the rising cost of petroleum-based insecticides, (ii) the adverse effect upon the environment which the broad spectrum chemical agents have had, and (iii) the high degree of specificity and therefore of control possible with biological agents.

The application of viral insect pathogens will undoubtedly increase over the next few years. Insect pathogens are commodities of very high value and may be considered as being relatively independent of raw material costs. However, the cost of developing effective formulations and of testing them may be very high.

There is a small but real base for the development of biological insecticides in Canada. An example of a nucleus of expertise in forest pest control using biological agents such as *Bacillus thuringiensis*, is the Forest Pest Management Institute of Environment Canada at Sault Ste. Marie.

Nevertheless, basic research in insect physiology, pathogen-host relationships and insect viruses is still required, and there is a real shortage of insect physiologists. The research is of a nature requiring long-range funding, but has the potential for major spinoffs and industrial development in the Canadian context.

Pharmaceuticals

The production of new and existing pharmaceuticals and biologicals will be markedly affected by the advent of biotechnologies. Advances in genetic engineering, microbial genetics and fused-cell techniques have already begun to make radical changes in this product area. New products and processes will increase the availability and improve the economics of current pharmaceuticals manufacture.

In Canada, the pharmaceutical industry is small and the insignificant level of R and D within this area stems largely from the negative impact that particular patent legislation has had over the last decade. In 1969, changes were introduced into the Patent Act by the enactment of Bill C-102. This amendment, Section 41, empowered the Commissioner of Patents to grant compulsory licenses for the importation and manufacture of pharmaceuticals produced by processes protected by Canadian patents.

Although the original intention of Section 41 was to reduce the cost of pharmaceuticals to the consumer, in fact, the overall saving is less than one dollar per capita per year at the manufacturer's level. At the same time the royalty rate for compulsory licenses is uniformly and arbitrarily set by the Commissioner at 4 percent of net selling price, regardless of the cost and the nature of research effort involved.

In our view, Section 41 has been the major cause of decreased R and D investment in Canada by the pharmaceutical industry. As long as this legislation remains in force, it is unlikely that any R and D investment will be made by the industry to capitalize upon the opportunities offered by biotechnology in pharmaceuticals.

While Canadian biotechnological R and D expertise exists in the field of pharmaceuticals, few examples of interdisciplinary approaches can be discerned and little focus is evident. The importance of pharmaceuticals as an element of national security cannot be overlooked and a political decision to maintain self-sufficiency in certain aspects of health care products could radically alter Canada's biotechnological efforts in this area, economic arguments notwithstanding.

It should be noted, however, that the area of biologicals, such as vaccines and blood products, is one in which Canada has traditional strengths and, by virtue of her own R and D efforts, is close to self-sufficient with significant export markets. The development of new as well as improved products in this area is vitally dependent on biotechnology.

Liquid and Gaseous Fuels

The bioproduction of substitute fuels to replace hydrocarbon-based conventional crude oil derivatives is currently a controversial issue in some quarters. We nevertheless feel that this application of biotechnology could be of significance in determining alternate energy strategies for Canada.

The biotechnological production of fuel-grade alcohol from renewable resources as well as from the carbohydrate content of waste products has received the most attention. Similar activity directed at the fermentation of agricultural, industrial and domestic wastes to produce methane may well open new avenues to this energy source. Moreover, methods for the biological production of hydrogen are receiving increased emphasis. However, the ultimate direction and focus which all of these approaches take will depend upon the formulation of a clear Canadian strategy on renewable energy.

Single Cell Protein

The potential for the production of protein for food from microbial cultures (Single Cell Protein or SCP) has been known for several years. Because the production of SCP does not

require conventional agricultural technology or animal husbandry practices, its use as a protein source has received attention in some countries.

There is still considerable debate throughout the world as to the economic viability of SCP production. Research and development activities have therefore centred upon improving the economics of production, including process development, substrate selection, microbial selection and possible genetic manipulation to eliminate undesirable by-products. In some European countries, large scale production of SCP for animal feeds is just beginning. The economic viability of these first operations in competition with soybean and fish meals remains to be demonstrated. In North America, however, where soybean is plentiful and low in price, it is questionable whether SCP will become economically viable.

The economic viability of SCP enterprises could be changed by the application of appropriate government incentives, but from Canada's position as a net food exporter it is not clear that an initiative into SCP production is warranted. This situation might alter, however, if (i) the world market price of soybeans and other feeds increases substantially, or if (ii) SCP production were to be tied to the utilization of industrial or agricultural wastes which otherwise carry a significant penalty in terms of cost of disposal. In any event, the development and subsequent sale of biotechnologies related to SCP production could provide an opportunity to capitalize upon any existing Canadian expertise in this area.

4. BIOTECHNOLOGY: A DEVELOPMENT PLAN FOR CANADA

4. BIOTECHNOLOGY: A DEVELOPMENT PLAN FOR CANADA

Biotechnology represents an important element in Canada's future industrial and economic development. The development of biotechnology is just beginning and the major economic impact of its applications will probably not be seen for close to a decade. Nevertheless, it is vitally important to implement, at this stage in Canada's effort in biotechnology, a plan of development which will ensure that this country may vigorously pursue appropriate biotechnological opportunities and at the same time be in a position to capitalize upon developments in other countries.

THE PLAN OBJECTIVE

The objective of the proposed biotechnology development plan is to create in Canada the climate which will encourage the establishment and growth of a variety of industries which are built upon biotechnology. To achieve this objective it is necessary to create a strong, viable research and development infrastructure with which to support an emerging biotechnological industry.

THE PLAN ELEMENTS

The biotechnology development plan is composed of a number of elements, each of which is important and must be pursued vigorously if the objective of the plan is to be achieved. These elements are outlined below.

1. Commitment

The long-term nature of the research and development activity required for the successful exploitation of biotechnology, together with the perceived impact which this area of technology could have upon Canada's industrial future, underscore the importance of developing a national strategy embodying long-term commitments to biotechnology by all sectors. While industries, universities and governments, both federal and provincial have significant roles to play in working together towards the promotion and development of biotechnology in Canada, it is the responsibility of the federal government to take the lead in coordinating and catalyzing the national commitment. However, the nature of biotechnology as an area of high technology is such that, unless a long-term approach and commitment are made by each sector, any short-term strategies or token activities may impede rather than promote this area of technology in Canada.

2. Industrial Stimulation

The lack of a significant biotechnological industry in Canada requires that fundamental measures must be instituted at this stage in order to encourage the formation of this industry and to nurture it during its early years. Biotechnology, as an area of high technology, offers the opportunity for the development of new industries as well as the revitalization of existing ones. Therefore, a variety of measures must be initiated in order to ensure that the entire range of industrial activity, from R and D to commercialization, is vigorously pursued.

For an established company, one which is profitable and therefore paying taxes, tax write-offs for research and development investment are recommended. For a new, developing company, direct government financial assistance, government procurement as well as tax shelters to make available venture capital for biotechnology, would seem to be most appropriate.

Technology transfer between sectors represents an important element in the development of a Canadian biotechnological industry. Existing government programs which promote technology transfer will be important factors. Technology transfer is a people-oriented activity; therefore, a strategy which encourages the continued interaction between scientists, technologists and industrialists will greatly enhance the potential for effective technology transfer and thereby enhance the degree of industrial application.

3. Interdisciplinary Science Base

An interdisciplinary science base is the foundation of the techniques comprising biotechnology. The scientific effort in Canadian universities and government establishments has been badly eroded over the past decade. A major long-term financial commitment from both federal and provincial sources must be forthcoming to ensure that Canada can actively participate in rapid biotechnological advances.

It will be important, however, to ensure that scientific development in Canada is properly nurtured. Biotechnology is an interdisciplinary area and the scientific knowledge for its development must come from an interdisciplinary environment. Moreover, the group approach to scientific and technical developments in biotechnology must be fostered in order to guarantee the creation of the appropriate critical masses upon which any true development can grow.

4. Manpower

The successful development of a Canadian biotechnological industry and the accompanying research capacity will depend largely upon the availability of appropriate manpower. Unless sufficient appropriately trained people are available, the demand which is already beginning to emerge in Canada will have to be

satisfied from foreign sources. Reliance on other countries, however, for the supply of biotechnological manpower will not be practical in the long term because of the rapid expansion of biotechnological activity world-wide and the concomitant increase in the demand for manpower.

As the Canadian biotechnological industry develops, demands for certain skills will increase. Of particular need will be interdisciplinary skills which will provide graduates from both the universities and technical colleges with the flexibility to adapt and thus contribute to the broad range of opportunities presented by biotechnology.

Shortages in many of the skills required for biotechnological development are already apparent in Canada. Until a sufficient domestic supply of such people becomes available, immigration priorities must be established to ensure the rapid entry of designated individuals crucial to the build-up of a Canadian biotechnological manpower capacity.

Training of students is only one component of the biotechnology manpower picture. Existing scientists and technologists must be offered the opportunity to acquire new skills relevant to biotechnology and its developments.

5. Directions

There are many industrial opportunities presently offered by biotechnology. As biotechnology matures, there will undoubtedly be many more opportunities presented; this explains why so much long-term investment capital is currently being directed into building up biotechnology capacity throughout the world.

For Canada, the major priority is to establish a strong industrial R and D infrastructure capable of assessing and pursuing the range of opportunities offered by biotechnology. In addition, the Task Force feels that Canada should pay special attention to (i) biotechnological developments related to Canada's resource sectors, with particular emphasis placed on nitrogen fixation, novel aspects of cellulose utilization, plant strain development, treatment and utilization of wastes, and mineral leaching and metal recovery; and (ii) the development of needed health care products as necessary elements in the country's future social as well as economic development.

6. Regulation

Government regulation is capable of either enhancing or inhibiting the growth of science, of technology and of the industrial sector. For the future development of biotechnology in Canada, it may be necessary to enact, modify or eliminate certain regulations or legislation which, if not addressed, will leave Canada at a serious disadvantage relative to the rest of the world with respect to industrial investment in and exploitation of biotechnology.

Section 41 of the Patent Act and the compulsory licensing provisions of subsections (3) to (16) have had a devastating effect upon investment in pharmaceutical research and development in Canada. (See Pharmaceuticals p. 26) At a time when other countries of the world are strengthening their patent systems to ensure the patentee a fair return on investment and thereby stimulate industrial development, this provision in Canadian patent law has essentially eliminated all new pharmaceutical product development in Canada. Since biotechnological developments are expected to have a strong effect on both the food and pharmaceutical sectors, and since both these sectors are covered by Section 41, the Task Force expresses great concern over the negative effect that this compulsory licensing provision will have upon the overall development of biotechnology in Canada.

Bill C-32 is a piece of legislation presently before Parliament, which, if enacted, would provide the plant breeder or developer with control over the multiplication and sale of reproductive material. These rights would then be similar to those accorded a patent or copyright. The intent of this legislation, which is similar to that currently in place in other countries, is to encourage greater investment activity in plant breeding in both the private and public sectors.

Biotechnology, which will have a major impact on the development of new plant varieties, could receive considerable impetus from the adoption of this legislation. However, the compulsory licensing provision of the Bill, if administered in a fashion similar to Section 41 of the Patent Act, could negate any positive intention of the Bill towards industrial development, and as a consequence would most certainly inhibit, if not eliminate, this high priority area of biotechnological development for Canada.

Guidelines for the handling of recombinant DNA molecules, animal viruses and cells, currently administered by the Medical Research Council, reflect the current state of knowledge surrounding these materials. As new knowledge has surfaced, these guidelines have, through a flexible system of modification, evolved accordingly. Legislation embodying these guidelines would reduce the present flexibility and would be inadvisable in an area of science and technology experiencing rapid change.

Since the guidelines are not directly binding upon industry, a system of voluntary compliance should be considered, and could be made mandatory for the receipt of government assistance.

7. International Collaboration

World-wide escalation of investment in biotechnology began about a decade ago, but the greatest acceleration has come within the last five years. West Germany, the United States and Japan have been the leaders in this activity, but recent impetus

has also been evident in Great Britain, France, Scandinavia, Switzerland and New Zealand among others. It is vitally important for Canada to have access to this activity and at the same time to be able to contribute to it. The progress of biotechnology in Canada will be accelerated through the furtherance of international collaborations and measures must therefore be instituted to facilitate all forms of interchange between scientists, technologists and planners from Canada and the rest of the world.

In addition, Canada's participation in Third World development could be furthered through collaboration with developing nations on biotechnological applications in food and energy production, as well as other areas of natural resource utilization.

8. Organization

In order to facilitate the implementation and operation of a development plan for biotechnology in Canada, a national organization must be established to:

i) oversee, coordinate and evaluate federal resource allocations in biotechnology;
ii) maintain contact with global developments in biotechnology;
iii) provide advice to the federal government on a range of issues related to biotechnology development (legislation, international commitments, etc.);
iv) ensure a flexibility in the development plan to allow it to be modified as circumstances dictate; and
v) provide, to all sectors, information and guidance on Canadian programs and activities in biotechnology.

It is important that this organization include industrial representation and be open to advice from all interested parties. At the beginning, the pathways of advice could take the form of national symposia and later evolve into a series of advisory boards.

RECOMMENDATIONS

1. ***Commitment*** — To signify its commitment to biotechnology and the need for a long-term development strategy, *it is recommended that the federal government announce the establishment of a ten-year National Biotechnology Development Plan.* For the first year of the Plan an allocation of $33 million is recommended, rising to an average annual expenditure of $50 million (current dollars) over the lifetime of the Plan. This expenditure is viewed as a necessary catalyst to encourage industry and provincial governments to make substantial investments in biotechnology.[6]

In its formulation the Plan would have eight elements: (1) commitment, (2) industrial stimulation, (3) interdisciplinary science base, (4) manpower, (5) directions, (6) regulation, (7) international collaboration and (8) organization.

2. ***Industrial Stimulation*** — The appropriate investment climate is a major factor in the growth of a Canadian biotechnological industry. As an area of high technology with pay-offs expected in the long-term, biotechnology presents financial risks which must be softened if investment capital is to be attracted. To reduce the cost and thus lower the risk and increase the rate of return of investing in biotechnological R and D, *it is recommended that the present 100 per cent write-off for R and D expenditures as well as the current 50 percent deduction for incremental R and D expenditures and other investment tax credits, all be replaced by a 150 percent write-off of all biotechnology R and D expenditures incurred.*

To attract new investment into biotechnology industries, *it is recommended that a tax shelter scheme be instituted such that investors in these industries be permitted a 100 percent write-off of investment expenses against income from any source.* The investors should be individuals or businesses whose principal business activity is not biotechnology, and they should also be eligible for the 66 2/3 percent incremental investment write-off similar to that formerly allowed for frontier oil and gas exploration investments.

Governments, both provincial and federal, can provide considerable stimulation to the growth of the biotechnology industrial sector and its related service sector through specific procurement policies. *It is therefore recommended that the Biotechnology Research and Development Panel (see Organization p.40), in maintaining its watch over developments in biotechnology, advise governments of the need for specific procurement action to assure biotechnology industrial growth.*

The federal government can and should play a significant role in the growth of small and medium biotechnological industries through direct financial assistance. *It is therefore recommended that an additional $6 million be added to the 1981-82 budget of the Enterprise Development Program of the Department of Industry, Trade and Commerce for this purpose.*

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(6) The Task Force is fully aware that the total amount recommended may represent a significant financial burden for the government, at a time of fiscal restraint. Nevertheless, the Task Force feels that this is a very conservative estimate of required federal expenditure, given the wide range of potential applications of biotechnology, the importance of biotechnology to Canada's future industrial development, and the almost complete lack of existing Canadian biotechnological capability.

Technology transfer is an important element in high technology industrial growth. To promote the transfer of advances in biotechnology from government laboratories to the private sector, *it is recommended that an additional $5 million be added to the recently consolidated PILP-COPI program for 1981-82. It is also recommended that to promote technology transfer from university laboratories to industry $0.7 million be added to the PRAI program of the NSERC for 1981-82.*

To stimulate a greater interaction among scientists, technologists and industrialists, and thereby create the opportunity for future technology transfers, *it is recommended that the NSERC, the MRC, and the NRC, with the possible participation of other government departments and agencies, encourage multi-sectoral conferences, workshops and seminars across the range of possible topics related to biotechnology.*

An additional $0.3 million is recommended to be added to the conference budgets of each of these agencies for 1981-82 to permit greater access by groups and individuals to these events, as well as help to defray some of the anticipated overhead costs.

A final aspect of industrial stimulation is salary support for research personnel in industry or people working on projects relevant to a particular industry. The IRAP program of the NRC has been most effective in this regard and *it is recommended that the 1981-82 total budget for this program be increased by $3 million to provide additional salary support for biotechnology researchers.*

3. ***Interdisciplinary Science Base*** — An interdisciplinary science base is the foundation upon which biotechnology rests. The techniques of genetic engineering, fused cells, plant-cell culture, enzyme and enzyme systems, and process and systems engineering will develop and mature only if built on a firm interdisciplinary science base. The universities and some government research establishments are the principal locations of biotechnological research in Canada. For the universities *it is recommended that for 1981-82 the budgets of the NSERC and the MRC be increased by $4.7 and $2 million respectively to provide operating funds for research focussed on the needs for industrial biotechnology.* These Councils are also encouraged to use these additional funds to foster a group or team approach to research, thereby focussing the effort, encouraging interdisciplinarity and leading to the eventual recognition of biotechnological centres of concentration.

The success of concentrating resources in certain universities will depend to an extent upon the response of the provincial governments to these initiatives. Therefore, as part of the national commitment to biotechnology, negotiations between the provincial governments and the Granting Councils are encouraged.

The Division of Biological Sciences and the Prairie Regional Laboratory of the National Research Council are other sources of Canada's future scientific developments related to biotechnology. To strengthen this effort, *it is recommended that an additional eight person-years and $1.5 million be added in 1981-82 to the resources of the Division of Biological Sciences, and six person-years and $0.8 million to the Prairie Regional Laboratory.*

4. ***Manpower*** — The training and acquisition of the appropriate skilled people are major elements in Canada's biotechnological future. Both the NSERC and the MRC should be encouraged to provide interdisciplinary training support for biotechnological manpower. To accomplish this, *it is recommended that the NSERC and the MRC receive $3 million and $1.4 million respectively for 1981-82, these sums being in addition to existing allocations.* These funds should also be used to encourage graduate training in government and industry research establishments in association with a Canadian university graduate school.

The lack of a Canadian biotechnology industrial sector suggests that biotechnology industrial post-doctoral opportunities in the short-term in Canada will be minimal. *It is recommended that both the NSERC and the MRC seek ways in which to provide industrial postdoctoral support tenable outside Canada.* A return clause will be necessary, however, if this manpower pool is to be retained for Canada's future.

Providing the appropriate training to the development of a valuable biotechnology manpower base is the responsibility of the universities, technical colleges and their respective provincial governments. The shaping of curricula and other aspects of course development in biotechnology are in immediate need of attention and the Task Force encourages these partners to proceed without delay in developing a suitable educational environment for biotechnology.

Another aspect of the biotechnological manpower situation in Canada is the current shortage of the appropriate skills to meet immediate demands. To ensure that industrial, government and university research establishment development is not unnecessarily impeded, *it is recommended that immigration priorities reflect the urgent needs for these skills.* The recent relaxation of immigration quotas for skilled workers announced by the Minister of Employment and Immigration is acknowledged as being an important step in this regard.

5. ***Directions*** — At this initial stage in the National Biotechnology Development Plan the major priority is to concentrate on building up the scientific and technological capacity in the country. The Task Force believes that it would be premature to designate

particular institutions as biotechnology centres. Nevertheless, the identification and strengthening of centres of concentration must be pursued as the Plan progresses.

There are several areas of application of biotechnology which, because of their potential impact upon the Canadian economy, must be strengthened in order to allow Canada the opportunity to take fullest advantage of their future benefits. These areas are: (i) nitrogen fixation, (ii) novel aspects of cellulose utilization, (iii) plant strain development, (iv) treatment and utilization of wastes, and (v) mineral leaching and metal recovery. Moreover, special attention must also be paid to the health care applications of biotechnology, as a major factor in Canada's social as well as economic future.

For nitrogen fixation, *it is recommended that the current nitrogen fixation programs within Agriculture Canada and the Prairie Regional Laboratory of the NRC be combined and located exclusively in Saskatoon and Ottawa. For 1981-82 it is further recommended that five person-years be added to each of these establishments and the budget of each be increased by $1 million.* For forest-related nitrogen fixation research, *it is recommended that the Canadian Forestry Service of Environment Canada submit a plan to the Biotechnology R and D Panel (See Organization p.40) for developing and at the same time concentrating resources in this area.* The plan should be submitted within six months of initiation.

To encourage the application of biotechnology to the utilization of cellulose and cellulosic residues and wastes, *it is recommended that Environment Canada and the NRC undertake, in collaboration with industry and the Pulp and Paper Research Institute of Canada, a study of the appropriate means whereby the activities of each department might be combined and strengthened in order to enhance the existing efforts of the forest products industry in this field.* Similar studies, in collaboration with appropriate industrial representatives, should be made with regard to the treatment of wastes and residues from other industries, which should be encouraged to investigate the application of biotechnology to the conversion of their wastes into useful products. *It is further recommended that Environment Canada should examine means for strengthening existing research on the applications of biotechnology to the control of pests,* particularly forest pests, in which connection the study should examine how the Forest Pest Management Institute at Sault Ste. Marie can be strengthened as one means of addressing some of the problems of preserving the cellulosic base. This study and the aforementioned studies on utilization of cellulose and cellulosic residues and wastes, should be presented to the Biotechnology R and D Panel (see Organization p.40) within six months of initiation.

From Canada's perspective, one area of future promise in biotechnology which must be pursued is plant strain development. *It is therefore recommended that ten person-years as well as $1 million be added in 1981-82 to permit Agriculture Canada, through the exploitation of biotechnology, to augment its current plant strain R and D activities.*

For mineral leaching and metal recovery, *it is recommended that Energy, Mines and Resources Canada seek ways of promoting the development of the existing Canadian strengths in this area and that $1 million for 1981-82 be made available for this purpose.*

6. ***Regulation*** — *It is recommended that Section 41 of the Canadian Patent Act be eliminated.* It is feared that if this section of the Patent Act is retained it will have a decided negative effect upon biotechnological R and D investment by the private sector. Also encouraged is a general review of the Canadian Patent Act to ensure that it is not leaving Canada at a disadvantage relative to other nations with respect to industrial R and D investment.

It is further recommended that Bill C-32, Plant Breeder's Rights, be given careful consideration by the Federal Government. Since biotechnology will have a heavy impact upon future plant breeding and since the development of new plant strains is an important area of biotechnology for Canada, the Task Force finds the concept of greater protection for the plant breeder worth pursuing. However, the compulsory licensing provision of the Bill, if it fails to guarantee the plant breeder adequate compensation for his development costs, will, it is feared, result in a situation analogous to that described above for Section 41 of the Patent Act, namely, the eradication of the plant breeding industry in Canada.

Finally, the current guidelines for the handling of recombinant DNA molecules, animal viruses and cells are deemed to be adequate, given the current understandings associated with these materials. *It is recommended, therefore that the MRC continue to administer the guidelines and to refine them as warranted in the light of developments in knowledge on the subject. Moreover, it is recommended that a system of industrial voluntary compliance with the guidelines be established by HWC.* This system should also include specifications as to how HWC will protect proprietary information which has been voluntarily submitted.

7. ***International Collaboration*** — It is imperative that Canada maintain strong linkages with biotechnological developments in other countries. The great breadth of biotechnology dictates that no one country can become a master of all facets of this area of high technology. Collaborations must therefore be pursued at as many levels as are feasible. *It is recommended that the NSERC, the NRC and the MRC encourage, through existing programs, those university scientists willing to pursue international collaborations in biotechnology.*

It is also recommended that government scientists be encouraged to pursue international as well as domestic collaborations in biotechnology. At this time it is premature to establish a particular budget for support of international collaborations in biotechnology. Nevertheless, as the National Biotechnology Development Plan evolves, it may be necessary for the Biotechnology R and D Panel (see Organization p.40), in consultation with External Affairs, to develop a more formal program which takes into account Canada's need to maintain its awareness of biotechnological advances elsewhere and Canada's potential future contributions to Third World development using biotechnology.

8. ***Organization*** — *It is recommended that a Biotechnology Research and Development Panel be established to coordinate and act as the focal point of the National Biotechnology Development Plan.* The Panel would be empowered to oversee, coordinate and evaluate the distribution of the resources allocated to the National Biotechnology Development Plan, to maintain surveillance over world-wide developments, to advise the government on matters related to biotechnology and to ensure effective communication among all sectors. *It is further recommended that the Minister of State for Science and Technology determine the exact structure of the Panel: industrial representation should be a major element in its composition.*

Several Provincial governments have already launched initiatives into the biotechnology area. But there is considerable danger that these efforts could fail, owing to the limited financial, manpower and industrial resources currently available for biotechnology in Canada. *It is therefore strongly recommended that the Provinces be encouraged to participate collectively in the deliberations and activities of the Panel.*

As part of the input into its decisions the Panel should hold an annual national symposium on recent biotechnology developments, policy and program issues and related matters. As the National Biotechnology Development Plan matures, specific Advisory Boards, possibly representative of different regions of the country, could evolve as a more effective means of providing multi-sectorial advice to the Panel.

5. CONCLUSION

5. CONCLUSION

Biotechnology, as an area of high technology, will be a major factor in world industrial development in the years ahead. The resource sectors, Canada's traditional source of economic strength, will be the ones most heavily influenced by biotechnology. Unless Canada is successful in developing and maintaining a biotechnological industrial capacity, our competitiveness in energy, mining, forestry and food and agriculture will erode.

Biotechnology is characterized at the moment by five technical areas: genetic engineering, enzymes and enzyme systems, fused-cell techniques, plant-cell culture, and process and systems engineering. These areas will continue to evolve and mature through interdisciplinary advances in many areas of science.

The revitalization of existing industries or the establishment of new ones through biotechnology can only be accomplished if there is an adequate scientific and technical base upon which to draw. The existence of a strong, viable, interdisciplinary science base and its effective coupling to technological development will therefore be crucial elements in the growth of a biotechnological industry in Canada.

The horizons for biotechnology are long-term, with many of the major potential benefits not expected for at least a decade. Nevertheless, unless Canada begins immediately to improve the climate for industrial R and D investment in biotechnology, and at the same time build its biotechnological capability, few of the opportunities and benefits will be available to her in the years ahead.

The federal government has an important role to play in the future of biotechnology in Canada. As a performer of R and D as well as the major influence upon the national climate for investment in R and D, the federal government must immediately take the initiative of catalyzing and coordinating the activities of all sectors, thereby ensuring that biotechnology is appropriately promoted and developed in Canada. This initiative must, in the view of the Task Force, be a commitment in the form of a ten-year national development plan. This plan must take cognizance of the weak and fragmented character of Canada's current biotechnological efforts, it must recognize the interdisciplinary and multi-sectorial nature of biotechnology, it must ensure that both new and existing industries are encouraged to invest in biotechnology, it must proceed to strengthen the science and manpower bases so intrinsic to biotechnological development, it must capitalize upon Canada's resource strengths and promote the effective management of those resources and it must emphasize the importance of fostering international linkages in

biotechnology. Finally, it must develop a regulatory climate which, while protective of the rights and concerns of the individual citizen, does not leave Canada at a disadvantage with respect to scientific and industrial developments in other countries.

Such a plan would permit Canada the opportunity to develop biotechnologies indigenous to her own needs, to assess and adapt biotechnologies developed elsewhere and to develop a biotechnology industrial infrastructure capable of competing on an international scale.

Biotechnology today represents an opportunity to develop for tomorrow. Immediate initiation of a national development plan for biotechnology is a necessary element in beginning Canada's preparation for the future.

ANNEX

ANNEX
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ABBREVIATIONS

COPI	Cooperative Projects with Industry
DNA	Deoxyribonucleic Acid
ENFOR	Energy From the Forest
HWC	Health and Welfare Canada
IRAP	Industrial Research Assistance Program
MOSST	Ministry of State for Science and Technology
MRC	Medical Research Council
NRC	National Research Council
NSERC	Natural Sciences and Engineering Research Council
PILP	Program for Industry/Laboratory Projects
PRAI	Project Research Applicable to Industry
R and D	Research and Development